

Ethics, legal, social, counselling Reproduction, genetics and the law



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Abstract

Both reproductive medicine and genetics are seeing rapid, and in some instances revolutionary, medical and scientific advances. Courts have been called upon to resolve a variety of novel disputes arising from these areas, and more can be anticipated as these technologies continue to develop and their use becomes more widespread. This article discusses some of the most relevant areas of the law and litigation that currently bear on reproduction and genetics or that may be anticipated to do so in the future. Specific developments and judicial decisions addressing them include: legal theories of wrongful birth and wrongful life and their application to children born with genetic impairments; a physician's duty to warn family members about a relative's genetic disease; disputes over reproductive materials and non-reproductive cells and tissues; unauthorized genetic testing in the workplace; and genetic discrimination. It is hoped that this discussion will be of value to medical and legal professionals and policy makers who work with these concepts in the increasingly inter-related fields of law and medicine.

Keywords: genetic discrimination, misuse of reproductive material, PGD, reproductive genetics, reproductive technology law, wrongful conception

Introduction

Reproductive genetics, meaning the use of reproductive and genetic technologies to both provide prospective parents with information about a future child and to avoid having a child with a genetic abnormality, is a rapidly evolving area of medicine. As with many of the new reproductive technologies, courts have been called upon to resolve a variety of disputes arising from reproductive genetics, and more can be anticipated as these technologies continue to develop and their use becomes more widespread.

Reproductive genetic testing has been used for several decades to inform prospective parents about their risk of producing a child with a genetic disorder. Prospective parents can be screened to determine if they are carriers of a genetic disease ('carrier screening') before they initiate pregnancy. Most of the time, however, carrier screening occurs once pregnancy has already begun. In addition, prenatal testing can be performed, in which the fetal DNA is tested for genetic defects using amniocentesis or chorionic villus sampling (CVS).

In past decades, the number of genetic tests available was fairly limited. Now, however, there are tests for over 1000 genetic diseases available either commercially or as part of research (GeneTests@<http://www.genetests.org>), and the availability of these tests has influenced standards of medical care. For example, in 2001, the American College of Obstetrics and Gynecology and the American College of Medical Genetics recommended that the genetic test for cystic fibrosis be made available to all couples seeking preconception or prenatal care, and offered to all couples in ethnic or racial groups considered at higher risk for carrying the CF gene (Grody *et al.*, 2001).

In the past 10 years, scientists have developed a method called preimplantation genetic diagnosis (PGD) to test embryos directly for genetic defects before they are implanted into a woman's uterus. This technology requires that the woman undergo IVF in order to obtain eggs and create the embryos for testing. In PGD, embryologists remove one or two cells from an embryo and perform genetic testing on the DNA from the cell(s). Those embryos found to be free from the genetic defect

can then be selected for implantation. In the future, scientists may even be able to correct genetic abnormalities before birth using germline gene therapy.

Both assisted reproduction (often referred to as 'assisted reproductive technology') and genetics have raised novel issues for the courts over the past few decades. Donor insemination, which predates most of the newer, more complicated technologies, is not routinely considered a form of assisted reproduction from a medical perspective. The combination of these technologies has increased the range and complexity of the decisions judges have been called upon to make. Assisted reproduction has raised a variety of legal issues including: (i) control and custody of embryos; (ii) access to assisted reproduction services; (iii) parentage of children conceived through donor gametes; and (iv) liability for misappropriation of gametes and embryos.

Genetic technologies have also raised many legal issues, including: (i) ownership and control of genetic material and information; (ii) misappropriation of genetic material; (iii) discrimination based on genetic information, e.g. in employment or insurance; (iv) liability for failure to detect or warn about a genetic disorder through genetic testing; and (v) privacy rights and compelled testing.

In considering legal questions in the context of novel reproductive genetic technologies, courts are likely to draw upon existing precedents (previously decided cases in relevant, if not identical, contexts) for guidance. For example, the legal theories of 'wrongful birth' and 'wrongful life', discussed below, first arose before the advent of prenatal and preconception genetic testing, but have since been asserted in these contexts. This article will provide a discussion of the most relevant areas of the law and litigation that currently bear on reproductive genetics or that can be anticipated to do so in the future.

Court cases arising from children born with genetic or other birth defects

Carrier screening and prenatal testing for some genetic conditions, such as Tay Sachs disease and Down syndrome, have been available for many years, and before prenatal genetic testing was available, doctors employed other tests to assess fetal health. There is thus a large body of case law in the United States arising from lawsuits against health care professionals following the birth of a child with an impairment that was either not discovered in the fetus through prenatal testing or not foreseen prior to conception by proper screening or diagnosis of the parents. Legal theories or 'claims' supporting such lawsuits are generally referred to as wrongful birth and wrongful life claims, although various courts may characterize such theories simply as negligence, professional negligence, or medical malpractice.

Wrongful birth claims are those brought by parents alleging that, but for the defendant's negligence, they would have aborted or never conceived the child. Wrongful life claims are those brought by (or on behalf of) children alleging that, but for the defendant's negligence, they would not have been born.

Claims for wrongful birth and wrongful life are most often brought against the physicians who performed or failed to offer or perform prenatal testing or preconception genetic testing, hospitals or medical practices that employed such physicians, and genetics laboratories that provided or failed to provide the testing services.

There is also a large body of law involving children, healthy or otherwise, born following a failed sterilization, abortion or pregnancy diagnosis. Courts throughout the US differ widely in their terminology, characterizing these claims variably as 'wrongful conception', 'wrongful pregnancy', professional negligence, medical malpractice, or simply negligence. (For ease of reference, all such claims will be referred to here as wrongful conception.) Wrongful conception claims are generally filed by parents against the physician (and the hospital or medical practice employing him or her) who performed the negligent sterilization or abortion or who failed to diagnose a pregnancy. These cases and the analyses the courts apply may provide relevant precedent for cases involving reproductive genetics testing since parents will similarly claim that, 'but for' the missed diagnosis, they would not have attempted a pregnancy. This theory may be an even stronger legal basis for such claims, since in almost every instance the pre-conception procedure will have been undertaken for the very purpose of hoping to avoid conceiving a child without a genetic abnormality, and therefore both causation and injury may be provable.

Before turning to particular cases, it should be noted that the same legal principles apply regardless of whether the child's impairment is genetic or not, and often regardless of when it was discovered (i.e. after birth, during pregnancy, or pre-conception), so that older court decisions may provide guidance in newer areas as well. As can be seen in subsequent sections of this article, these legal principles have been invoked by courts in the relatively few cases that have been brought involving new reproductive genetic technologies.

It should also be noted that the claims, or 'causes of action', meaning the legal theories that a court will permit to support a lawsuit, are typically governed by state law, and therefore vary from state to state. Thus, this overview should be used as a guide rather than definitive evidence of the status of the law in a particular jurisdiction. Finally, this overview focuses primarily on court decisions from the highest state courts, since these provide 'precedent' (rules or interpretations of law), which lower courts in that same state must follow. Some federal court decisions that have interpreted a state's laws are also reviewed, since those interpretations are often given great weight within a state.

Wrongful birth court decisions

Within a state, cases are initiated in a trial (lower) court, which renders a decision that is binding on the parties to the dispute, but not binding as legal precedent for other or future cases in that state. If the losing party appeals, the decision may be reviewed by an intermediate appellate court and/or the state's highest appellate court. The ruling by a state's highest court must be followed by all other courts within that state. In some circumstances, such as when the disputing parties are from different states and the amount of money involved in the

dispute is sufficiently large, a federal court may have 'jurisdiction', meaning the legal authority to hear the case. In those situations, the case may instead be brought and tried in federal court. Wrongful birth claims are ruled by state, not federal law, so a federal court hearing a wrongful birth case will be called on to interpret the applicable state law. The ruling by a federal court is not binding on state courts, but is often given significant deference.

Twenty-six states have high state court or federal court decisions that recognize and uphold wrongful birth claims (**Table 1**). These courts almost universally allow recovery of damages for extraordinary expenses due to the child's affliction, but prohibit recovery of normal child-rearing expenses. The decisions differ regarding whether damages are recoverable for the parents' emotional distress.

Sixteen of these wrongful birth cases involved children with a genetic impairment, such as Down syndrome, Tay Sachs disease, or cystic fibrosis (**Table 1**). Seven involved children with non-genetic congenital defects such as rubella syndrome or birth defects resulting from cytomegalovirus. One case involved spina bifida, the causes of which are not clearly understood, and in two cases in Nevada the courts did not discuss whether or not the impairment had a genetic component. The nature of the impairment (genetic or non-genetic) generally has no bearing on the legal outcome in wrongful birth actions.

A minority (six) of state high courts or federal courts that have considered the issue have refused to recognize wrongful birth actions (**Table 1**). All six such cases involved children with genetic impairments. These courts rejected such claims either because of a specific statute prohibiting them, or based on the court's judgment that the existence of a human life, even with severe impairments, cannot constitute a cognizable legal injury, i.e. an injury that the law is willing to redress.

There are also a significant number of states (19) that have no state high court or federal court case law addressing the validity of wrongful birth claims in those states. The majority of these 19 states have no intermediate appellate case law either. Those few states with intermediate appellate case law tend to vary in their approach to wrongful birth claims and damages in a parallel

manner to the states with high court decisions. Trial court decisions are not discussed here, because they do not carry the same precedential value as appellate cases.

Wrongful life court decisions

In contrast to wrongful birth claims, the vast majority (25) of states with state high court or federal court decisions have refused to recognize claims for wrongful life (**Table 2**). Of these, the majority (18) involved children with genetic impairments; the minority involved children with non-genetic congenital impairments. The overwhelming reason given for refusing to recognize wrongful life claims is the inability or unwillingness of courts or jurors to weigh the value of an impaired life against the value of non-existence.

Only four states have high state court or federal court decisions that recognize wrongful life claims. All of these cases, except the Washington case, involved children with genetic impairments. These decisions have generally allowed recovery of damages only for extraordinary expenses required to treat the child's ailment, and have not permitted recovery of general damages for having been born with an impairment.

As with wrongful birth, there are also a significant number of states (22) that have no state high court or federal court case law addressing the validity of wrongful life claims. Similarly, the majority of these states also have no intermediate appellate case law. Those relatively few states with decisions by an intermediate appellate court tend to vary in their analysis in the same manner as do the states with high court decisions. Here too, trial court decisions are not discussed because they do not carry the same precedential value as appellate cases.

Wrongful conception court decisions

The vast majority of states (32) have state high court or federal court decisions recognizing wrongful conception claims (**Table 3**). Of the 32 states, there are 35 state high court or federal court opinions, 33 of which are negligent sterilization cases, one is a failed abortion case (Pennsylvania), and one involved failure to diagnose a pregnancy (Alaska). Only six states reject such claims.

Table 1. State high courts' or federal courts' decisions on wrongful birth according to state.

Recognizing and upholding claims for wrongful birth

Alabama, Arizona, California, Colorado, Delaware, Washington, D.C., Florida, Idaho, Illinois, Indiana, Kansas, Maine, Maryland, Massachusetts, Nevada, New Hampshire, New Jersey, New York, Oklahoma, Pennsylvania, South Carolina, Texas, Virginia, Washington, West Virginia, Wisconsin

Based on cases involving children with genetic impairments

Alabama, California, Colorado, Delaware, Washington, D.C., Florida, Illinois, Indiana, Maine, Massachusetts, New Jersey, New York, Pennsylvania, South Carolina, Virginia, West Virginia

Based on cases involving children with non-genetic congenital impairments

Arizona, Idaho, New Hampshire, Oklahoma, Texas, Washington, Wisconsin.

Presence of a genetic component not discussed

Nevada

Refusing to uphold claims for wrongful birth

Georgia, Kentucky, Minnesota, Missouri, North Carolina, and Utah

No cases

Nineteen states have no court cases

Table 2. State high courts' or federal courts' decisions on wrongful life according to state.*Recognizing and upholding claims for wrongful life*

California, Maine, New Jersey, Washington

Refusing claims for wrongful life

Arizona, Colorado, Delaware, Florida, Idaho, Illinois, Kansas, Kentucky, Maryland, Massachusetts, Michigan, Minnesota, Missouri, New Hampshire, New York, North Carolina, Ohio, Pennsylvania, South Carolina, Texas, Utah, West Virginia, Wisconsin, Wyoming

Involving children with genetic impairments

Colorado, Delaware, Florida, Illinois, Kansas, Kentucky, Maryland, Massachusetts, Minnesota, Missouri, New York, North Carolina, Ohio, Pennsylvania, South Carolina, Utah, West Virginia

Involving children with non-genetic congenital impairments

Arizona, Idaho, New Hampshire, Texas, Wisconsin, Wyoming, Indiana

No law

Alaska, Alabama, Arkansas, Connecticut, Washington, D.C., Georgia, Hawaii, Iowa, Louisiana, Mississippi, Montana, Nebraska, Nevada, New Mexico, North Dakota, Oklahoma, Oregon, Rhode Island, South Dakota, Tennessee, Vermont, Virginia

Table 3. State high courts' or federal courts' decisions on wrongful life according to state.*Recognizing and upholding claims for wrongful conception (majority involving healthy children)*

Alabama, Alaska, Arizona, Arkansas, Connecticut, Washington, D.C., Florida, Georgia, Illinois, Indiana, Kansas, Louisiana, Maine, Maryland, Massachusetts, Minnesota, Missouri, New Hampshire, New Mexico, North Carolina, Ohio, Oregon, Pennsylvania, Rhode Island, Tennessee, Utah, Vermont, Virginia, Washington, West Virginia, Wisconsin, Wyoming

Upholding claims in cases involving children with impairments

Connecticut (orthopedic abnormality), Florida (congenital defects), Georgia (club foot), Louisiana (albinism), North Carolina (genetic defect), Ohio (birth defect), Pennsylvania (neurofibromatosis)

States also including costs of rearing healthy child in full

New Mexico, Oregon, Washington

States allowing costs of rearing healthy child but offset by benefits of rearing child

Arizona, Connecticut, Maryland, Massachusetts, Minnesota

Denying recovery since it was not a foreseeable consequence of negligent sterilization

Ohio, Louisiana

Birth impairment considered when assessing other damages but not allowing costs of child rearing

Florida, Georgia, Pennsylvania

Also accepting costs of child rearing

North Carolina

Case-by-case approach

Connecticut

Rejecting claims for wrongful conception

Iowa (failed abortion), Kentucky, New York, Oklahoma, Texas (last three for negligent sterilization) (all involving healthy children)

Including both healthy children and those born with congenital impairments

Texas

Healthy children only

New York, Oklahoma, Kentucky, Nevada

No law

California, Colorado, Delaware, Hawaii (decision but only addressed civil procedure issues, not underlying action), Idaho, Michigan, Mississippi, Montana, Nebraska, New Jersey, North Dakota, South Carolina, South Dakota

Of the majority of states that recognize wrongful conception claims, most of the cases (28) involved healthy children. Relatively few (seven) involved impaired children. In those cases involving healthy children, most states (21) do not allow recovery for child-rearing expenses, but only for any actual damages related to the sterilization or other procedure(s), pregnancy, and birth, which generally include medical expenses, pain and suffering of the mother related to pregnancy and childbirth, lost wages of the mother, and 'loss of consortium' (financial compensation for the loss of companionship, in this context usually of a spouse). A minority of states also allows recovery of the costs of child rearing, either in full or offset by the benefit derived by the parents of raising a healthy child (**Table 3**).

In the seven cases involving children born with impairments, two states denied any recovery related to the birth defect because the birth defect was not a foreseeable consequence of the negligent sterilization. Three states allowed consideration of the defect in assessing other damages (such as emotional distress or special medical needs) but did not allow child-rearing expenses. One state allowed recovery of the costs of raising the child without any offset for benefit to parents. Another state adopted a 'case-by-case' approach where the court found the value of the benefit (of having a child) should mitigate or offset the damages to the extent equitable.

A minority of states (six) have state high court or federal court cases rejecting claims for wrongful conception. Of those six states, all addressed claims involving healthy children, and one of them, Texas, addressed claims involving both healthy children and children with congenital impairments. All of these cases were negligent sterilization cases, except for the Iowa decision, which was a failed abortion case. The courts rejected the claims based on a lack of injury or damage to the parents, refusing to consider the birth of a healthy child to be a legally cognizable injury. The court in Iowa rejected such claims on the basis that the benefits of a healthy child outweigh the associated monetary burdens. Texas, the one state addressing both healthy children and impaired children, rejected all such claims and concluded that a birth defect makes no difference to the legal analysis because it is not a foreseeable consequence of a failed sterilization.

A relatively small number of states (13) have no state high court or federal case law on wrongful conception (**Table 3**).

Defendants in wrongful conception or wrongful birth cases may seek to deny culpability on the basis that the plaintiff consented to the treatment or the procedure. While a court may examine a consent document to see whether it addresses the conduct at issue, generally courts have found that such documents do not remove or reduce a professional's liability resulting from negligent conduct, such as medical malpractice. Courts have determined that, as a matter of public policy, professionals should not be able to protect themselves from their own negligence, as opposed to any inherent risks of a procedure or condition, through disclaimers or waivers that attempt to transfer the risks to patients or non-professionals. Some courts have also noted that patients are not in an equal bargaining position with a medical professional and it would be unfair to enforce a waiver for that reason. The extent to which language in signed consent forms that outline risks may

limit professional exposure is therefore unclear, particularly because state laws and courts vary regarding the degree to which they take such forms into account.

State statutes addressing wrongful birth/wrongful life

A state's laws can comprise both statutes and court decisions. A state can develop a body of common law from that state's court decisions, and then pass a statute that essentially codifies that body of common law, supplants the common law, or complements it, depending on the wording of the statute. Following the enactment of a statute, court cases may then start building a body of law interpreting that statute. Ten states have enacted legislation (**Table 4**). In six of these, state laws prohibit actions for both wrongful life and wrongful birth. Two prohibit only wrongful life actions. One limits damages for the birth of, and to a child harmed as a result of, professional negligence. At least three of the states that have enacted statutory bans on wrongful birth or wrongful life claims have done so in support of each state's stated public policies of respecting the right to life of all humans, born or unborn, healthy or unhealthy, and disfavoring abortion. The statutes in these states provide that a cause of action shall not arise based on a claim that, 'but for' the act or omission of another, a person would have been aborted. Maine's legislative intent is reflected in its statutory language: '(i)t is the intent of the Legislature that the birth of a normal, healthy child does not constitute a legally cognizable injury and that it is contrary to public policy to award damages for the birth or rearing of a healthy child' (Me. Rev. Stat. Ann., 2003a). A few states have enacted statutes that prohibit recovery of child-rearing expenses in actions for wrongful conception or negligent sterilization (Me. Rev. Stat. Ann., 2003b; Mich. Comp. Laws, 2004).

Wrongful birth/life cases arising through assisted reproductive technologies

Wrongful birth and wrongful life issues have arisen in a small number of cases involving children born through the use of assisted reproduction, donor gametes, and PGD.

Court decisions involving PGD

Wrongful life issues were identified and rejected by a court in one of the only two cases reported to date involving PGD (both were trial level cases involving children born with cystic fibrosis after mistaken assurances that the tested embryo was not affected). A Massachusetts trial court rejected claims brought on behalf of an affected child and by his parents, and refused to recognize the injury based on a new legal claim of 'preconception tort' (Doolan vs IVF America, 2000). Instead, the court characterized the claims as ones for wrongful life, which it ruled were precluded by precedent in that state. The court further found that the defective gene itself, not the defendant physicians, had caused the defect, a distinction that also carries over to cases involving donor gametes with undetected or unreported genetic abnormalities, as discussed below. The court's opinion did not address whether the consent forms adequately outlined the risks of PGD or whether PGD

Table 4. State statutes addressing wrongful birth and/or wrongful life.*Enacted statutes*

California, Indiana, Maine, Michigan, Minnesota, Missouri, North Dakota, Pennsylvania, South Dakota, Utah

Prohibit both wrongful life and birth

Michigan, Minnesota, Missouri, Pennsylvania, South Dakota, Utah

Prohibit wrongful life only

Indiana, North Dakota

Limit damages for professional negligence only

Maine

Prohibit recovery of child-rearing expenses for wrongful conception or negligent sterilization

Maine, Michigan

was considered an experimental procedure. The second PGD case involved access to certain research records and is discussed below in the context of breach of professional duty. A small number of other alleged failures of PGD have resulted in lawsuits, but have settled and therefore no court decisions have followed.

Court decisions involving genetic abnormalities from donor gametes

Two cases have been brought against professionals who failed to identify or inform intended parents of a genetic abnormality in their chosen sperm or egg donor, after which a child was born with a serious genetic abnormality. In one case, a California sperm bank failed to report a sperm donor's family history of kidney disease, although he had allegedly noted it on his donor intake form. The child was subsequently born with autosomal dominant polycystic kidney disease (APKD) (*Johnson vs Superior Court*, 2002). In the second, a New York assisted reproduction medical programme overlooked and therefore failed to notify the intended parents that their selected egg donor had tested positive as a carrier for cystic fibrosis (*Paretta vs Med. Offices for Human Reproduction*, 2003). They conceived and their child was born with the disease.

In the California sperm bank case, multiple legal issues were raised and argued, including whether or not the bank was protected under state statutes designed to protect health care providers. The California trial court held that the sperm bank was exercising professional skills as a health care provider, even if not engaged in a physician-patient relationship, and therefore fell within that state's statutory protections. The court rejected the parents' arguments that the bank was operating solely as a commercial business selling spermatozoa. As with the PGD cases, the court found that the donor's genes, and not the defendant sperm bank, caused the child's genetic abnormalities, and therefore the sperm bank could not be held legally responsible for the child's disease. Following California's established law, the court rejected the child's claim of wrongful life. The New York court also rejected both general damages and arguments that the defendant professionals, rather than the donor, had 'caused' the child's abnormalities. The New York trial court also characterized and rejected the claim as one for wrongful life, refusing to recognize either a tort of 'negligent preconception

or pre-implantation counselling' or any obligation to perform PGD, and relied on older New York case law which disallows general damages.

Other court cases involving reproductive genetics

In addition to the extension of wrongful birth/wrongful life theories to encompass new reproductive technologies such as PGD, other issues are beginning to arise from genetic testing, genetic information, and genetic material in the context of assisted reproduction. The remainder of this article provides a summary analysis of those relatively few cases, as well as a limited number of recent cases that, although not directly involving reproductive genetics, present related issues and thus may be helpful in understanding legal approaches that may be used to resolve conflicts involving reproductive genetics. Given the small number of cases and the fact that state laws differ, the cases are more illustrative of current approaches than predictive of how specific future disputes may be resolved.

Court decisions involving failure to warn family members

Cases involving reproductive genetics are likely to arise from a patient, a patient's parent, or a research subject claiming that a health professional caused harm by his or her negligent or intentional act or failure to act. In order to find a health professional liable, he or she must be found to have had a duty to the plaintiff(s) and to have breached that duty by falling below the applicable standard of care, and the breach has to have caused the alleged injury. Courts must therefore define the types of relationships that give rise to a duty, the scope of that duty, the standard of care owed as a result of that duty, and when the statute of limitations (the time during which the lawsuit may be initiated) for a breach of that duty begins to run. Where a child has resulted from the negligent act, some courts have followed their state's wrongful birth, wrongful life, or wrongful conception analyses, as discussed above, while others have analysed the case under privacy, negligence and medical malpractice principles.

Failure to provide accurate genetic information has been the basis of claims against both treating physicians and researchers. Courts have frequently looked to whether or not

the defendant had a relationship with, and thus a duty to, the plaintiff patient or family member. Researchers, as opposed to treating physicians, are generally held not to have a physician-patient relationship with their research subjects, and thus have been found not to have a duty to warn patients or family members as to a genetic vulnerability. For example, in a case involving a state-wide randomized, blinded control study of newborns for cystic fibrosis, the researchers were found not liable to the parents or younger affected sibling for not learning of, or warning the parents about, the older child's positive test (*Ande vs Rock*, 2002). The plaintiffs had been part of a state-wide cystic fibrosis research protocol in which excess blood was drawn from all newborns and used to test them for cystic fibrosis. Under the research protocol, the parents of half of the newborns were told of a positive test and those infants were put on a nutrition plan, while the test results of the second half were not revealed. The goal of the study was to ascertain whether nutritional supplements slowed the progression of cystic fibrosis. The plaintiffs were in the group who were not notified, and therefore did not learn of their child's diagnosis until the child reached the age of 2 years, and after they were pregnant with a second child. That child was also diagnosed with cystic fibrosis, and one of the parents' claims was that had they been given the newborn screening results, they would not have conceived their second child.

In a widely cited non-genetics research case, however, a Maryland appellate court came to the opposite conclusion (*Grimes vs Kennedy Krieger Inst.*, 2001). That court found that a 'special relationship' was created between the researchers and their minor subjects and therefore negligence and breach of contract claims could be brought on behalf of minor plaintiffs against researchers who conducted an allegedly non-therapeutic research experiment (i.e. one that provided no benefit to the research subjects) and involved more than minimal risk. The court noted that minors were vulnerable research subjects, and that informed consent by parents on behalf of their children for non-therapeutic research raised serious legal, moral and ethical concerns.

In one of only two reported cases involving PGD, where a child was born with cystic fibrosis after a mistaken assurance that the tested embryo was not affected, an Illinois intermediate appellate court refused to allow a plaintiff access to the IRB-approved research protocol documents, ruling they were privileged by state statute and not designed to facilitate truth seeking in private malpractice cases (*Doe vs Masonic Med Ctr*, 1998). The couple had sought the acknowledged experimental procedure to ensure their second child would not be born with the disorder after their first child was born with it.

Courts have come to different conclusions regarding a treating physician's duty to a patient's immediate family members. For example, in a few reported assisted reproduction cases a husband has sued his wife's physician for performing artificial insemination with donor spermatozoa without the husband's consent. Two courts, based on their state's relevant statutes, have come to opposite conclusions on the question of whether or not the physician owed a duty to the patient's husband (*Kerns vs Schmidt*, 1994; *Shin vs Kong*, 2000).

Inherited conditions also raise the issue of whether and whom a treating physician has a duty to warn, how that duty, once defined, is met, and how to balance that duty with a duty of confidentiality to the patient. While it is impossible to generalize or identify trends given the limited number of cases and variety of state laws and standards, certain analytical issues are evident. A few cases are illustrative.

In a Minnesota case (*Molloy vs Meier*, 2004), that state's highest appellate court ruled that there was a duty to warn a biologically related parent in a case involving a child with fragile X. After the child was born, her mother remarried, and the mother and new husband were falsely reassured, based on incorrectly read test results, that the child did not have fragile X. The mother then proceeded, with her new husband, to conceive a child who was also affected with fragile X. The court affirmed the lower appellate court's finding, including a duty to warn family members about the first child's condition existed, which would be met by telling either biological parent. The intermediate court explicitly noted that there was no duty owed to the wife's new spouse, because he had no biological relationship with the first child, a finding the parties did not appeal and which was thus not ruled on. The higher court noted that the parties conceded the duty to warn would have been met by informing an appropriate 'contact person', such as either of the custodial parents or Molloy as the non-custodial biological parent. In allowing the claim, the court framed the parents' claim as one for wrongful conception, and not as wrongful birth or life (both of which had been prohibited by state statute). The court also addressed a statute of limitations issue, ruling that under the circumstances the damage did not occur and thus the statute did not begin to run until the conception of the second child. The intermediate court acknowledged that doing so created the possibility that cases involving inherited genetic defects might not be discovered and therefore filed until years, and potentially decades, after the wrongful act. That potential problem, it found, was an issue to be addressed by the legislature.

In two cases involving adult-onset inherited genetic disorders, courts found a duty to warn family members, although the requirements the courts imposed for meeting that duty differed. First, in a Florida case brought by the adult daughter of a thyroid cancer patient (*Pate vs Threlkel*, 1995), the court found the parent's treating physician had a duty to warn family members, but that such duty would be met by the physician warning only the patient. The court explicitly acknowledged that the disorder, medullary thyroid carcinoma, was a 'genetically transferable disease'. The court found that most patients would tell family members, and that any other requirements could compromise confidentiality and be unduly burdensome on a physician.

Second, in a New Jersey case (*Safer vs Estate of Pack*, 1996), an intermediate appellate court found a broader duty to warn the plaintiff. The case was brought by the adult child of a patient who had died (when the plaintiff was a child) of colon cancer resulting from multiple polyposis, an inherited syndrome that in virtually all untreated cases leads to colon cancer. Noting that it disagreed with the Florida court's ruling on how that duty could be met, the New Jersey court found that in some instances a duty to warn of a genetic risk might not be satisfied solely by informing the patient rather than his or her

family members directly. Finding 'a duty to warn of avertable risk from genetic causes' is 'by definition a matter of familial concern', the court found a duty was owed to 'members of the immediate family of the patient who may be adversely affected by a breach of that duty'.

Both the Florida and New Jersey cases were brought by the child of a patient and neither court further defined the terms 'immediate' or 'family member'. The Florida court did note that the prevailing standard of care, meaning the average degree of skill and care exercised by members of the medical profession in the same or similar locality given the present state of medicine, created a duty 'that is obviously for the benefit of certain identified third parties', to whom a duty is therefore owed, including 'a patient's children [who] fall within the zone of foreseeable risk'. The court also noted that the standard of care, as in any malpractice case, is determined by a consideration of expert testimony on the question of the accepted or prevailing medical custom in and for that type of community.

Given the extremely limited case law, the scope of a health care provider's duty to warn family members of genetic risks remains an unsettled area at this time.

Court decisions involving compelled testing to determine parentage

Genetic testing, both voluntary and compelled, has been widely available for many years and literally thousands of cases have been reported that involve testing in the context of proving paternity for the purpose of requiring child support or proving identity in criminal prosecutions, both of which are outside the scope of this article. Since the advent of the assisted reproductive technologies, a few cases have been reported in which one party seeks to compel genetic testing to determine the parentage of a child. Efforts to legally compel such testing have for the most part been unsuccessful. Courts have generally followed established state law on when paternity testing is and is not permitted, and most states require that the person seeking to have the child tested must first demonstrate a minimal, 'threshold' level parental relationship, or attempted relationship, to attempt to prove their own parentage of the child. Thus, in a lawsuit brought by a woman alleging that her embryos had been implanted into the wrong woman, a court refused to compel genetic testing of 14-year-old twins who had never lived with, or developed any relationship with, the plaintiff who claimed to be their genetic mother (Prato-Morrison vs Doe, 2002). Similarly, in a lawsuit brought by a man who in a written contract previously acknowledged being a sperm donor, a court refused to test twins being raised by a lesbian couple (Lamaritata vs Lucas, 2002). However, as discussed below, where gamete or embryo 'mix-ups' may be involved and the claim is brought promptly, genetic testing may be part of the litigation.

Court decisions involving disputed use of reproductive material

Disputes over the use of reproductive material, including eggs, spermatozoa and embryos, can arise in a variety of contexts, such as contested parentage of born children, custody of frozen embryos, misappropriation of gametes by health care

providers, or control over gametes or tissue by donors, intended parents, and researchers. All raise standard of care issues for the professionals involved and thus require a determination of what level of care professionals are to be held to. Discussed here are only those cases and theories with an impact on reproductive genetics.

Cases involving parentage or custody disputes over already-born children are typically analysed using legal theories of tort, negligence, or breach of contract, as well as applicable family law principles or statutes. These cases are largely beyond the scope of a summary of reproductive genetics law. Cases can, however, arise following the alleged wrongful implantation of reproductive material, for example, if gametes or embryos are mixed-up during IVF. In such cases, in addition to lawsuits between patients to resolve competing claims of legal parentage, claims will probably be filed against the health professionals involved in causing the mix-up. When an anonymous egg or spermatozoon is utilized, claims may be limited to those brought by one set of parents against the professional who supplied the genetic material or performed the medical procedures. These latter cases may be analysed under a 'wrongful life' theory, and in some cases damages for healthy children have been rejected if the state does not recognize this theory (Harchiner vs Univ of Utah, 1998). Where mix-ups result in competing claims of parentage, family or probate litigation has been highly publicized, and involves difficult and novel judicial decisions about legal parentage [for example, Perry-Rogers vs Fasano, 2001; Perry-Rogers vs Obasaju, 2001; Robert vs Susan, 2003], *app. denied* 2003 Cal LEXIS 6671 (Cal., 2003)].

One dispute involving control and use of healthy donor gametes in Texas illustrates the inadequacy of the law, even in a state with laws addressing control of donor eggs or parentage of the resulting children. In that case, a commercially recruited egg donor learned that her donated eggs had been 'split' or shared between two couples at the same IVF clinic at the suggestion of their physician. The donor had entered into a written legal agreement with the first couple only, which reportedly contained an explicit provision that only that couple could use the eggs. The donor and the second couple, who had created but then been precluded from using the embryos created with some of those eggs, each filed lawsuits against the physician and broker. In recommending the sharing arrangement, the physician reportedly had relied on Texas law, which states that egg donors are not parents of children resulting from their donated gametes (Texas Family Code, 2003). At least two multi-party lawsuits were filed, by the donor and by the second couple. The donor's suit was reportedly settled for an undisclosed financial settlement from the doctor and clinic and the second couple, who ultimately were allowed to use the embryos, were dismissed from that lawsuit (Houston Chronicle, 2002). A lawsuit between the broker and physician resulted in a verdict for the broker (TX 3/22/05).

In another unique fact pattern illustrating the complexity of these issues, a single woman and married couple litigated the legal parentage of a child born to the single woman, whom she intended to be from a donated embryo. Instead the physician accidentally transferred an embryo created for the married couple as part of their own infertility treatment (Robert vs

Susan, 2003). Because the couple had used donor eggs to create their embryos (and their one resulting child to date), the child at the centre of the dispute was the genetic child of the married man but not of his wife. The trial court has ruled that the single woman was the child's mother and the married man was the father (and not a donor as she had argued, since he never intended to donate his spermatozoa or embryos). That court further found that the father's wife, who had no genetic or gestational claim to the child, had no legal claim to maternity. The court did not address the fact that the wife was the intended mother of any child who might result from the embryos she and her husband had created. The single mother also sued the physician, resulting in a settlement.

In the mid-1990s, a highly publicized series of both civil and criminal court cases arose involving three physicians at the University of California-Irvine's Centre for Reproductive Health. It was discovered that, without their patients' knowledge or consent, the physicians had taken eggs and embryos from reportedly hundreds of patients, and implanted them in other patients. Drs Ricardo Asch, Jose Balmaceda and Sergio Stone were all criminally charged based on allegations of insurance fraud and false income tax return filings. Two of the doctors fled the country; Dr Stone was convicted and served time in jail. Civil suits were filed by and against the university, which settled the majority of over 100 separate patient lawsuits brought against it based on research misconduct and misappropriation of gametes, embryos and funds by the physicians (see <http://www.uci.edu/fc/chronology.html>). The scandal ultimately led the California General Assembly to pass the nation's first law making it a crime to steal human eggs and embryos (Welch, 2000).

In one of the very few reported court decisions stemming from the scandal, a couple sued another family to try to determine if they were the genetic parents of 14-year-old twins. The trial court refused to order blood tests or visitation, and dismissed the case. That court's ruling was upheld on appeal, with the appellate court ruling that no link to the twins had been shown, but that, even if the couple suing had shown such a link, the best interests of the teenage children was to dismiss the case (*Prato-Morrison vs Doc*, 2002).

There have been a growing number of cases involving control over frozen embryos or pre-embryos, usually following a couple's divorce. The term pre-embryo is often used to clarify in-vitro fertilized eggs that have not been implanted or gone beyond the very early stages of development (Jones and Veeck, 2002). One notable trend has been toward not permitting the use of frozen embryos for procreation over the objection of a spouse or a former spouse, notwithstanding any prior consent or agreement by the parties. A very recent jury trial ended with a finding in favour of the former husband who claimed an IVF programme transferred previously frozen embryos to his wife to have a second child without his knowledge or consent, and contrary to his wishes (*Gladu vs Boston IVF*). The couple had previously conceived twins at the IVF programme, using fresh embryos created with the man's spermatozoa and donor egg. At issue was the language and status of the cryopreservation consent document he signed at the time the embryos were created. He argued it was a contract, and required the programme physicians to obtain his consent at the time of any

subsequent transfer. The IVF programme contended the document was an informed consent document, and that the husband's prior consent, unless withdrawn by him, could be properly relied upon for subsequent embryo transfers. The jury found the physicians were not negligent but found the programme liable for breach of contract, and awarded the man US\$98,000 in child support, and US\$10,000 in emotional distress damages. The case illustrates the difficulty in categorizing documents and actions taken by patients and professionals in this area. Although this jury apparently found the consent document at issue was a legal agreement and did not give the programme the right to future implantations without subsequent consents, there is little precedent in this area and no assurance that other juries or courts would reach the same conclusion.

Some courts have questioned whether assisted reproduction clinics' cryopreservation forms are enforceable contracts, either between the patients and the programme or between the two patients themselves. The issue of enforceability can arise if there is a subsequent disagreement between a husband and wife over whether and how to use or dispose of their embryos or in a dispute between patients and a medical programme. Prior consents or agreements with medical programmes to use frozen embryos for other than procreation (i.e. for research or to discard) have generally been upheld. The very few reported disputes between patients and providers that have raised the issue of who has control of embryos have generally found that the patient, not the provider or clinic, had their right to control the embryos (*Del Zio vs Columbia Presbyterian Med. Ctr*, 1978; *York vs Jones*, 1989).

Access to and use of cryopreserved (frozen) spermatozoa, and the resulting parentage of children born from sperm cryopreserved prior to the death of the genetic contributor, have also been the subjects of recent litigation in a growing number of states. No consensus has yet emerged as to the degree of proof required prior to allowing, for example, a widow to use her deceased spouse's spermatozoa, or what requirements must be met prior to any resulting child being legally recognized as the child of the decedent. Massachusetts has set out a three-prong test for determining parentage and inheritance: proof of genetic parentage, proof of the decedent's consent to use the sperm, and proof of the decedent's intent to support the child (*Woodward vs Comm'r of Soc. Sec.*, 2002). A lower federal court in Arizona precluded posthumous recognition of legal parentage and denied Social Security survivor's benefits to twins conceived more than 10 months after their genetic father's death (*Gillett-Netting vs Comm'r of Soc. Sec.*, 2002), based on an interpretation of Arizona's intestacy laws (laws dealing with inheritance when one has died without a legal will) which expressly provided that only a child surviving the deceased parent or in gestation at the time of death may inherit. However, the appellate court reversed, finding the children were legal heirs and rejecting the applicability of the narrower laws. Whether posthumously conceived children are entitled to legal recognition and inheritance rights varies from state to state, depending on both that state's statutory inheritance laws and judicial interpretation.

Court decisions involving use of non-reproductive genetic material

Control and use of other bodily tissue or genetic material, specifically that contained in non-reproductive tissue, has been the subject of limited litigation to date. The most well known such case involved disputed ownership and control over the blood and tissue obtained from a patient diagnosed with hairy-cell leukaemia (*Moore vs Regents of Univ. of Cal.*, 1990). The treating physician had recommended the removal of the patient's spleen and thereafter, over a period of several years, had him return for further removal of blood and tissue. During that time, he and his colleagues successfully engaged in what the court described as 'potentially lucrative medical research' in which they developed and patented a cell line from the patient's T lymphocytes. The patient sued the treating physician and his colleagues who used the cells without his knowledge or permission.

The court ruled on two claims, allowing one while rejecting the other. First, the court ruled the claim could proceed on the basis of an alleged breach of the physician's disclosure obligations to his patient, and held that a treating physician must disclose any interests he has unrelated to his patient's health, 'whether research or economic, that may affect his judgment'. Second, the court rejected the patient's claim for conversion, meaning the unauthorized and wrongful exercise of control over another person's personal property (i.e. stealing). Noting that no court had ever imposed conversion liability for use of human cells in medical research, the court declined to 'impose a tort duty on scientists to investigate the consensual pedigree of each human cell sample used in research'. The court noted that it would compromise the exchange of scientific knowledge and threaten economic incentives to conduct important medical research to extend the theory of conversion to this circumstance. In the court's words, '[If] the use of cells in research is a conversion, then with every cell sample a researcher purchases a ticket in a litigation lottery'.

Another more recent, and still ongoing, case has also arisen in the context of a patent dispute (*Greenberg vs Miami Children's Hosp. Research Institute*, 2002). A patients' rights group sued medical researchers who discovered the gene for Canavan disease and then filed a patent for it without the group's knowledge. The plaintiffs argued that they had worked to gather tissue, identify families, and provide financial support to the defendant researchers, with the intention of assisting in the development of non-commercial advances in research and treatment. In their lawsuit, they claimed the defendants had breached a duty of informed consent, as well as a fiduciary duty to them, had been 'unjustly enriched' by the discovery and patent, and had fraudulently concealed and converted their property, as well as misappropriated 'trade secrets', in this case the list of patients suffering from the disease.

The federal court dismissed most of the patient group's claims. Similar to the few cases involving genetic information or material noted earlier, and noting with approval the case involving the patient with hairy cell leukaemia, the federal district court refused to impose a duty of disclosure on medical researchers regarding their economic interests in the absence of a physician-patient relationship, finding that such a duty

would be unworkable and would kill medical research. It also found no fiduciary relationship under applicable state (Florida) law, finding that such a relationship required both trust and acceptance, and the latter was missing. The court refused to find that undertaking the research itself created such a relationship. It also rejected any claim that the plaintiffs had a property interest in the tissue or resulting information and therefore rejected the conversion claim. The only claim allowed to stand was one for 'unjust enrichment', i.e. that the researchers may have unfairly been enriched in collecting their license fees since plaintiffs contributed so much to the research effort and would not have done so had they known the researchers intended to commercialize the testing process resulting from the genetic material they contributed to them rather than keeping any testing developed in the public domain. Because the plaintiffs alleged an ongoing research collaboration, as opposed to simply a donor-donee relationship, the court denied the researchers' attempt to 'seek refuge' behind the patent, as well as their argument that the plaintiffs had obtained what they sought: the isolation of the gene and the development of a screening test for it.

Genetic discrimination

As genetic testing becomes more widely available, concerns have been repeatedly voiced over the potential misuse of genetic information, particularly in the workplace and by health insurance companies. A number of state laws have been enacted that prohibit genetic discrimination in employment or insurance. As of late 2003, approximately 31 states had statutes prohibiting employer discrimination in the workplace, while 34 states had statutes strictly prohibiting the use of genetic information for risk selections and risk classification purposes. In addition, Arizona, Vermont, and West Virginia require actuarial justification for the use of genetic information; Texas bans use of genetic information in group health plans, and Alabama prohibits discrimination based on predisposition to cancer. HIPAA, the first federal law directly addressing genetic information, prohibits group health plans, usually meaning over 50 individuals, to discriminate in insurance on the basis of 'health status-related factor', including genetic information (National Conference of State Legislatures).

In October 2003, the US Senate unanimously passed the Genetic Information Nondiscrimination Act. Similar efforts in the US House of Representatives have been unsuccessful (Genetic Nondiscrimination in Health Insurance and Employment Act, 2003). Federal or state constitutional protections may also be implicated, and certain federal laws currently in place such as the Americans with Disabilities Act (ADA) (1990). The Title VII of the Civil Rights Act (2000) (as to employment only) may also afford some protections.

The ADA is potentially relevant to many legal issues that may arise concerning reproductive genetics, although to date there is little case law to guide its application to these issues. The ADA prohibits discrimination against individuals with disabilities (i) by employers of 15 or more employees; (ii) in public accommodations; and (iii) by state and local governments. Under the ADA, an individual has a disability and is therefore protected against discrimination if the individual (i) has an impairment, genetic or otherwise, that substantially limits a major life activity; (ii) has a record of

such impairment; or (iii) is regarded as having such impairment. While a broad discussion of genetic discrimination is beyond the scope of this article, the following discussion illustrates the ways in which genetic information may impact on employment, the provision of healthcare, and other contexts. For many people, reproductive genetic testing is the first time they are presented with the option to obtain genetic testing, both carrier and prenatal testing, and concerns about the possible future employment and insurance ramifications of learning this information for themselves and their offspring could influence their decisions.

Unauthorized testing in the workplace

To date, there have been relatively few reported court decisions involving genetic testing in the workplace, and none involving genetic testing by health insurers. Two notable cases have involved unauthorized testing by employers. Each case included claims under the ADA, which will be discussed below. But, the alleged surreptitious nature of the testing is noteworthy and is therefore separately addressed here. In the first case (*Norman-Bloodsaw vs Lawrence Berkeley*, 1998), a large research laboratory that was operating under a contract with the federal government and was jointly operated by the federal government and the state of California performed unauthorized testing of certain employees for both genetic and non-genetic conditions as part of a general health examination. Plaintiffs claimed that black employees were singled out for testing for the sickle-cell anaemia trait and women (for obvious reasons) were singled out for pregnancy tests. The plaintiffs claimed that the government-affiliated employer had violated their state and federal Constitutional rights to privacy, their statutory rights under Title VII of the Civil Rights Act, which prohibits employment discrimination based on race, colour, religion, sex, or national origin, and their rights under the ADA. After the trial court dismissed all of the plaintiffs' claims, the federal Court of Appeals for the 9th Circuit reversed in part, finding that the employees should be permitted to bring their claims based on Constitutional privacy violations and Title VII, and that factual issues existed regarding the privacy claims that should be resolved by the lower court. As discussed below, the court found that the ADA was not violated. The EEOC, however, takes the position that entrance exams such as medical tests are legal only if the examination is required of every individual hired for that particular job category (see <http://www.eeoc.gov/policy/docs/guidance-inquiries.html>).

The second case involved secret DNA testing of employees of the Burlington Northern Santa Fe Railway who submitted internal reports or work-related injury claims. The Equal Employment Opportunity Commission (EEOC) received complaints from employees that their DNA was being secretly tested by the railroad. The railroad required the test for employees who filed internal reports or submitted work-related injury claims based on carpal tunnel syndrome, and was conducted without the workers' knowledge and therefore without their voluntary and informed consent (Press Release EEOC, 2002). In that case, both the EEOC and the employees' union filed claims, all brought under the ADA, resulting in an agreed upon injunction and a US\$2.2 million settlement (EEOC vs Burlington N, 2002). That case is discussed more fully in the following section.

Cases brought under the Americans with Disabilities Act (ADA)

The ADA, genetics, and the workplace

The ADA prohibits covered employers from discriminating against employees with disabilities in the terms and conditions of employment and in benefits provided. The worker must be a 'qualified individual with a disability', meaning one who is able to perform the essential functions of the job, with or without reasonable accommodations. The Act, however, also has a specific 'safe harbour' exempting many of the decisions pertaining to insurance (including health insurance) from its antidiscrimination provisions. The impact of this safe harbour provision on the ability of employer-based health plans to deny coverage for assisted reproduction or based on the results of genetic tests is unclear.

The ADA's employment provisions also limit the ability of employers to ask employees about their disabilities and to conduct medical testing. Prior to a conditional offer of employment, the ADA prohibits medical examinations or tests. These are permitted following a conditional offer of employment as long as the tests are required of all applicants for a particular job category and significant restrictions on the use of the information gathered are complied with. In the laboratory workers' case discussed above, based on the lack of evidence that the employer had disseminated or used the information from the tests, the court found the employer had not violated the confidentiality and record keeping requirements in the ADA (*Norman-Bloodsaw vs Lawrence Berkeley Lab.*, 1998).

In the Burlington Northern case, the EEOC alleged violation of the ADA after receiving complaints from employees that their DNA was being secretly tested by the railway after they had either filed internal reports or submitted work-related injury claims based on carpal tunnel syndrome (Press Release, EEOC, 2002). The EEOC first sought a preliminary injunction against the railroad pending further investigation in which it asked the federal district court in Iowa to order the railroad to stop its testing practice (Press Release, EEOC, 2001a). In April 2001 the railroad entered into a settlement with the EEOC under which it agreed not to (i) require its employees to submit blood for genetic tests; (ii) analyse any blood previously obtained; (iii) evaluate, analyse or consider any gene test analysis previously performed on any of its employees; or (iv) retaliate or threaten to take any adverse action against any person who opposed the genetic testing or who participated in EEOC's proceedings (Press Release, EEOC, 2001b). A year later, the EEOC again filed suit based on the testing policy (EEOC vs Burlington N, 2002). EEOC and Burlington Northern entered into a settlement agreement, as part of which the railroad agreed to pay US\$2.2 million to 36 employees who had been directed to get tested (Hechler, 2002), but admitted no wrongdoing (Baker and Daniels, 2002). No court therefore had the opportunity to analyse the EEOC's allegations that the railroad had violated the ADA.

The EEOC has taken the position, as reflected in a 1995 compliance manual, that genetic testing violates the ADA and

that basing employment decisions on genetic testing is barred under the ADA's 'regarded as' prong of the definition of disability (Press Release, EEOC, 2002). Moreover, according to one EEOC Commissioner, the EEOC also takes the position that the 'mere gathering of an employee's DNA may constitute a violation of the ADA' (EEOC vs Burlington, 2002). According to the guidance, the 'regarded as' prong 'of the definition of disability applies to individuals who are subjected to discrimination on the basis of genetic information relating to illness, disease, or other disorders. Covered entities that discriminate against individuals on the basis of such genetic information are regarding the individuals as having impairments that substantially limit a major life activity' (EEOC Compliance Manual, 2000). The EEOC's action against Burlington Northern, discussed above, was consistent with this policy. However, no court has ever had occasion to consider the EEOC's interpretation; thus its enforceability is uncertain.

The employment provisions also prohibit employers from discriminating against an employee because of that employee's association with an individual with a disability. Although the courts have seldom construed this provision, it may apply to an individual who is a genetic carrier and has children with a genetic illness.

The ADA, genetics, and public accommodation

The ADA's public accommodation provisions apply to hospitals, clinics, and the offices of health care workers. In 1998, the Supreme Court held that an asymptomatic HIV-positive woman who was denied in-office dental treatment was disabled within the meaning of the ADA (Bragdon vs. Abbott, 1998). The Court held that HIV was a 'physical impairment', and that it substantially limited the 'major life activity' of reproduction, in that she would risk transmitting HIV to both her partner and child in the process. Thus the woman was disabled within the meaning of the ADA. By this logic, a person with genes causing a late onset disease (e.g. Huntington) or a carrier of a genetic mutation could be considered disabled, since they would risk transmitting their disease-causing genes to their offspring. Thus the Court's ruling may have implications for those with genetic conditions who are asymptomatic or to those who are carriers of genetic mutations. The courts, however, have not yet had an opportunity to address the application of the ADA to genetic carriers or individuals with asymptomatic genetic conditions.

One recent case brought and lost by a plaintiff involved a blind woman's claim that an IVF clinic that refused to continue artificial insemination treatments for her did so in violation of the ADA (Chambers vs Univ. Hosp., 2000). While the university defendant named in the lawsuit settled with the woman, the IVF clinic and physician went to trial, arguing that its refusal was not because of her blindness but because of concerns it had over her mental condition, hygiene and ability to childproof her home. A jury found in favour of these defendants, and the plaintiff has filed an appeal. Whether a health care entity can refuse to provide an individual with a particular genetic test or therapy, or with assisted reproduction, because of a genetic condition, however, has not yet been decided by the courts.

Conclusions

Just as reproduction and genetics are making rapid scientific advances, the legal issues emerging out of these developing technologies are complex and, in many cases, unique. To date, court decisions responding to these issues have been varying and sometimes contradictory from one jurisdiction to another. As these issues continue to arise, new and more nuanced legal rules are likely to be called for, based upon an understanding of both the law and science.

Medical professionals may find themselves thrust into an educational role, as judges and policy makers will need to become versed in the language and substance of reproductive science and genetics to reach reasoned results in their efforts to both respond to conflicts and to shape policy proactively in the form of legislation. Law and policy makers will also need to recognize the many connections to existing areas of the law and medicine while, at the same time, being cognizant of those aspects that are novel. Decision makers are likely to confront specific legal challenges involving determinations of causation of genetic and chromosomal abnormalities that will challenge existing legal frameworks involving wrongful birth, conception and life.

Existing legal time limits for bringing claims will probably prove inadequate for discovery of genetic abnormalities that may not appear for generations. Further challenges will involve defining the applicable standard of care and scope of duty, as well as discrimination and related issues and the applicability and limits of existing laws such as the ADA. The overarching challenge will be to reach wise decisions and create sound policies that are grounded in existing law while recognizing and responding sensitively to the new realities created by the advances in reproduction and genetics.

Acknowledgements

This article was originally commissioned by the Genetics and Public Policy Centre, a part of the Phoebe R Berman Institute at the Johns Hopkins University, which is funded through a grant from The Pew Charitable Trusts. The opinions expressed are those of the author and do not necessarily reflect the views of the Genetic and Public Policy Centre or the Pew Charitable Trusts.

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Received 26 January 2005; refereed 4 February 2005; accepted 17 March 2005.

China seeks good governance of research

As China opens its challenges in science to the wider world, the correct methods for administering the necessary stimuli for more research, financial and otherwise, and also a means of governance which is transparent and accountable, have to be determined. A brief article in *Nature* has outlined its intention to establish norms and a code of conduct to regulate the National Natural Science Foundation of China (NSFC). Decisions will be taken democratically, management based on law, and the use of funds will be effective. A senior policy maker stressed the intention to utilize overseas brainpower and attract overseas researchers to participate in basic research in China.

Models studied initially were based on analyses of legislation in other countries. These included legislative documents from Australia and elsewhere. The model finally adopted establishes standards for selecting experts to review peers and panels, and to manage programmes and results in a fair manner. The NSFC apparently follows

these principles already. Queries arise over the amount of money dedicated to research, which is still modest in relation to the total spent on research and development. One factor here concerns the very large number of projects requiring functions spreading over >8000 projects which apparently share ~US\$340 million. *Nature* nevertheless regards the new constitution as a positive step that may tempt many overseas Chinese scientists back to their home country. But other organizations, including the Ministry of Science and Technology and the Chinese Academy of Science, currently account for the largest research items and so carry responsibility for further progress. Perhaps they may follow the lead outlined by the NSFC in order to establish fair play and good governance from the outset of China's expansion.

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Editorial 2005 New accountability in China. *Nature* 434, 1053.

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